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The use of endoscopic band ligation in the primary prevention of bleeding in patients with ascites listed in the liver transplantation waiting list

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Abstract

Background. *Saving lives and preventing patients from dropping out of the waiting list for liver transplantation due to the progression of portal hypertension and the development of complications is an urgent task of transplantology in conditions of a donor organ shortage, which causes long waiting times for this operation.*

Aim. *To study the efficacy of endoscopic band ligation versus no intervention in the primary prevention of upper gastrointestinal bleeding and assess the impact on survival of patients with ascites listed in the liver transplantation waiting list.*

Material and methods. *A retrospective comparative study was conducted in patients with decompensated liver diseases with severe ascites and varicose veins, without a history of bleeding, when included in the waiting list for liver transplantation. Primary prevention of bleeding from varices was carried out in patients by means of endoscopic ligation of varicose veins (n=92, group 1); this intervention was not performed in other patients (n=89, group 2).*

Results. *The compared groups were comparable in demographics, clinical parameters, MELD and Child-Turcotte-Pugh scores, or the incidence of severe ascites. The study groups of patients did not have significant differences in the numbers of medium-size and large varices. The incidence of bleeding was significantly lower in the group of patients with endoscopic band ligation as a method of primary prevention than in the group of patients without this intervention (23.9% and 78.7%, respectively, p=0.0001). Patient survival was significantly higher in the group of patients who underwent endoscopic band ligation than in the group of patients without interventions, which was established using the Kaplan-Meier method (Log Rank=0.0001).*

Conclusion. *Primary prevention of bleeding from the upper digestive tract through endoscopic band ligation is an effective method of saving lives and preventing patients with ascites from dropping out of the liver transplantation waiting list in conditions of a donor organ shortageб which causes a long waiting period for surgery.*

Keywords: liver transplantation waiting list, ascites, bleeding, endoscopic band ligation

Conflict of Interest Authors declare no conflict of interest

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BP, blood pressure
CTP, Child-Turcotte-Pugh
EBL, endoscopic band ligation
EGDS, esophagogastroduodenoscopy
HCC, hepatocellular carcinoma
HE, hepatic encephalopathy
LC, liver cirrhosis
LT, liver transplantation
LTWL, liver transplantation waiting list
NSBB, non-selective β-blockers
PH, portal hypertension
USE, ultrasound examination, ultrasonography
VNT, varices needing treatment
VV, venous varix
WGO, World Gastroenterology Organization

Introduction

Portal hypertension (PH) forms the basis for the progression of liver cirrhosis (LC), which determines the development most of its severe complications, including ascites, bleeding from varices (VV) of the stomach and esophagus, and hepatic encephalopathy (HE) [1]. LC progression is predetermined by the severity of PH, the transition from the compensated stage to the decompensated stage that has clear clinical markers due to the

development of complications [2]. Patients with decompensated cirrhosis should be considered as candidates for liver transplantation (LT) [1].

The increase in the number of patients requiring LT worldwide, the expansion of indications, the undoubted success of this interventional procedure in saving lives contrast with a significant shortage of donor organs [3]. This, in turn, causes an increase in the number of patients with decompensated LC in the liver transplantation waiting list (LTWL) [4]. Undoubtedly, the global epidemic of COVID-19 and the health problems associated with this disaster have increased the waiting period for LT [5]. In 2021, in the regions of the Russian Federation, there was a revival of donor activity and the volume of transplant care to the population after its decline in 2020 against the epidemic of the new coronavirus infection COVID-19 [6]. So, during 2021 in the Russian Federation, 2272 potential recipients were in the LTWL, of whom 886 were included in the waiting list for the first time that year. At the same time, according to the register of the Russian Transplant Society, LT was performed in 618 patients in 2021, which undoubtedly reflected the imbalance between the number of patients awaiting LT and the number of surgical interventions performed [6].

An urgent task for specialists in the management of patients who have been in LTWL for a long period is to save their lives and prevent delisting due to the PH progression and the development of complications [7]. In patients with ascites and large VVs (>5 mm) who have a high MELD, Child–Turcotte–Pugh (CTP) liver injury severities, a primary prevention of bleeding through the use of non-selective β-blockers (NSBBs) or endoscopic band ligation (EBL) is recommended [1]. Patients with cirrhosis decompensation and progressive PH require regular screening. esophagogastroduodenoscopy (EGDS) to determine indications for EBL [1, 8, 9].

Aim

The aim of the study was to assess the efficacy of endoscopic band ligation versus no intervention in the primary prevention of bleeding and its impact on survival of patients with ascites included in the liver transplantation waiting list.

Material and methods

A retrospective comparative study was conducted at the Center for Surgery and Donation Coordination of the Rostov Regional Clinical Hospital after receiving the local Ethics Committee approval had been obtained. From a continuously updated electronic database that included 775 people who had been in LTWL for 1 to 66 months awaiting for LT, we enrolled in the study 181 patients with decompensated viral and alcoholic cirrhosis who discontinued NSBB for various reasons (absolute or relative contraindications, in particular diabetes mellitus, bronchial asthma, chronic obstructive pulmonary disease, as well as due to intolerance and/or side effects, a decrease in heart rate <60/min and/or systolic blood pressure (BP) <90 mm Hg against drug therapy).

Patients included in LTWL underwent endoscopy to screen for VVs with a high risk of bleeding, and with the need for therapy (“varices needing treatment” [VNT]) as recommended by the Baveno VI Consensus Workshop experts [8] and the World Gastroenterology Organization (WGO) [9]. The Guidelines of the International Ascites Club were used to determine the severity of ascites [10]. In all patients included in the LTWL, demographic and clinical data were obtained, clinical and biochemical tests were performed, hemostasis parameters were assessed. Laboratory parameters were monitored in patients in a stable condition with a 3-month interval

between re-examinations. Abdominal ultrasound examination (USE) was performed at the initial examination and after every 6 months of patient's being on the LTWL. The MELD-Na score [11] and CTP class [12, 13] scores were determined.

The inclusion criteria for patients in the study were: the presence of esophageal VV (VNT, grades 2 and 3); ascites, grade II or II, no history of bleeding from VV before inclusion in the LTWL; in patients with alcoholic etiology of cirrhosis: the presence of abstinence for at least within 3 months prior to inclusion in LTWL, being confirmed by the reports of narcologists and psychiatrists.

Exclusion criteria were the following: patients with malignancies with ascites development.

When included in LTWL, patients with HBV and HCV-associated cirrhosis were treated with antiviral therapy with nucleoside analogues and a combination of direct antiviral agents, considering the disease etiology. All patients received diuretics; in case of resistance, paracentesis was performed.

The EBL procedure was performed under sedation using an esophagogastroduodenoscope and an endoscopic venous varix ligation kit. VV ligation began at the gastroesophageal junction and proceeded proximally. During the EBL, from 2 to 4 or more rubber ligatures were used, depending on the VV size. EBL was repeated at 4 weeks after the first procedure and was repeated afterwards until all [8] VVs meeting the VNT criteria had been obliterated. After VV obliteration, control EGDS was performed every 3 months. In cases of a relapse development (a new VV occurrence), repeated EBL procedures were performed.

The first group of patients consisted of 92 patients who underwent EBL for primary prevention of VV bleeding, the second group included 89

patients without EBL. The primary endpoint of the study was the analysis of the EBL efficacy in the primary prevention of bleeding from VVs in the compared groups: with and without intervention. The secondary endpoint was a study of patient survival in the compared groups: with primary prevention of bleeding by EBL and without intervention.

Data analysis was made using the IBM SPSS Statistics (version 23) software. The Kolmogorov–Smirnov test was used to check the normality of the distribution of the obtained parameter values. The data obtained from samples with a normal distribution of values were presented by arithmetic means (M) and standard deviations (SD). The statistical significance of differences between the compared values in case of a normal distribution was determined by Student's t-test. For the values obtained for studied parameters different from a normal distribution, the nonparametric tests were used: Wilcoxon test for paired comparisons of dependent variables, Mann–Whitney (U-test), and Pearson's Chi-square for comparing independent variables. Quantitative data in samples with a non-normal distribution were expressed using the median (Me), and an interquartile range (IQR, the interval between the 25^{th} and 75^{th} percentiles). For qualitative data, frequencies and proportions (%) were calculated. The threshold criterion for statistical significance of differences was $p<0.05$. The efficacy of primary prevention of VV bleeding (the proportion of patients without bleeding) and the survival of patients in the compared groups (with and without intervention) was determined by the Kaplan-Meier method with the calculation of the logarithmic Log-Rank (Mantel-Cox) criterion.

Results

Tables 1 and 2 presents the demographic data, clinical, laboratory

parameters, calculated MELD-Na scores, and CTP classes in groups of patients with ascites who underwent EBL (n=92) and without interventions (n=89) during the period of being in LTWL.

As can be seen from the demographic and laboratory parameters presented in these tables, there were no significant differences between the compared groups. The liver damage severity as assessed by the MELD- Na score and LC classes by the CTP classification were comparable between the two groups of patients included in the study.

There were no significant differences in the cirrhosis etiology (viral, non-viral) between the compared groups. In patients included in the study, grade 2 ascites prevailed without statistically significant differences between the compared groups; the rates of grade 3 ascites were also comparable between the compared groups (30.4% and 32.6%, p=0.421). The compared groups had no statistically significant differences in the incidence of esophageal VVs classified as grade 2 and grade 3 VNT (p=0.14 and p=0.132).

Table 1. Comparative characteristics of parameters between the patients with endoscopic band ligation and without interventions (normal distribution and different from normal distribution)

Parameter	EBL (n=92) M±SD	Without EBL (n=89) M±SD	Statistical significance of differences
Normal distribution (M± SD)			
Age	48.41±11.16	48.47±11.69	0.97
Hemoglobin, g/L	113.43±23.38	112.55±25.61	0.83
Leukocytes, $x10^9$/L	3.31±0.73	3.19±0.65	0.24
Platelets, $x10^9$/L	75.96±33.78	70.27±37.34	0.28
Plasma albumin, g/L	36.23±4.54	31.99±4.95	0.59
MELD-Na	21.21±4.16	20.59±5.31	0.71
Different from normal distribution (Me; IQR)			

International normalized ratio	2.03 (1.63–2.45)	1.9 (1.71–2.08)	0.51
Bilirubin, μmol/L	67.0 (58.00–109.5)	64.0 (55.00–100.00)	0.43
Creatinine, μmol/L	91.0 (67.45–115.5)	89.0 (62.5–118.5)	0.67
Na, mmol/L	133.5 (119.0–147.5)	137.5 (105.5–169.5)	0.87

Table 2. Comparative characteristics of parameters between the patients with endoscopic band ligation and without interventions

Parameter	EBL (n=92) (%)	Without EBL (n=89) (%)	Statistical significance of differences
Male	49 (53.3%)	51 (57.3%)	0.585
Viral etiology of cirrhosis Alcoholic etiology of cirrhosis	50 (54.3%) 42 (45.7%)	46 (51.7%) 43 (48.3%)	0.635 0.549
Ascites, grade 2 Ascites, grade 3	64 (69.6%) 28 (30.4%)	60 (67.4%) 29 (32.6%)	0.415 0.421
VV, degree 2 (VNT) VV, degree 3 (VNT)	62 (67.4%) 30 (32.6%)	63 (70.8%) 26 (29.2%)	0.140 0.132
Child-Turcotte-Pugh, class B Child-Turcotte-Pugh, class C	4 (4.3%) 88 (95.7%)	7 (7.9%) 81 (92.1%)	0.357 0.315

VV, venous varices; LC, liver cirrhosis; VNT, varices needing treatment (varices to be treated).

While being in the LTWL (from 1.5 to 36 months), bleeding from the VV developed in 92 patients in the compared groups, of whom 22 patients were from the EBL group, and 70 patients from the group without interventions (23.9% and 78.7%, respectively, p=0.0001). The presented differences between groups of EBL use and without it were obtained in a comparative analysis of the proportion of patients without the VV bleeding occurrence by using the Kaplan-Meier method with determining the Log-Rank criterion (p=0.0001) (Fig. 1).

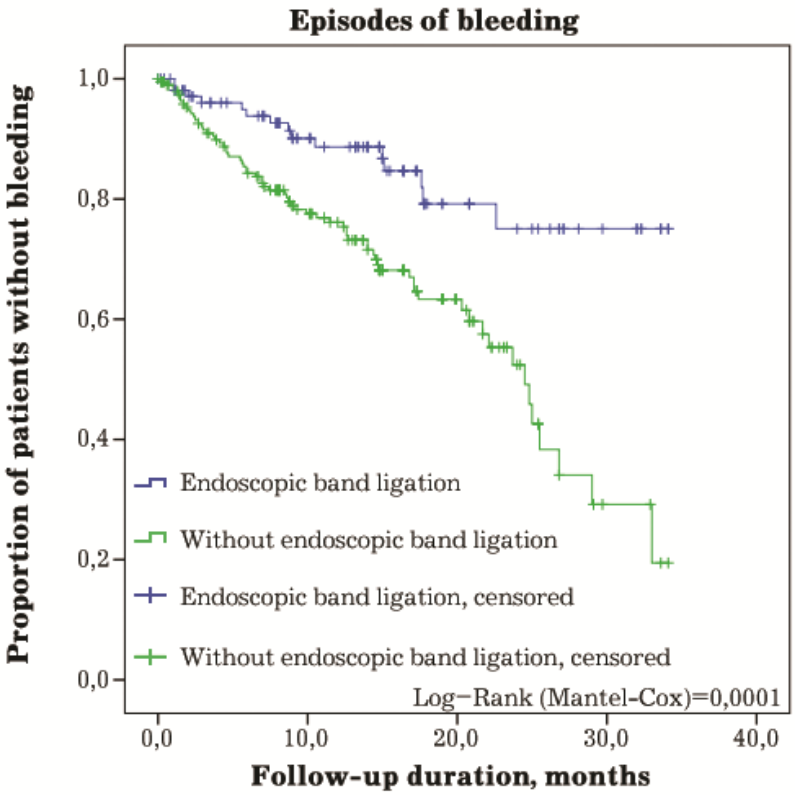

Fig. 1. Proportion of patients without bleeding after endoscopic band ligation or without intervention. (Kaplan-Meier method with Log-Rank criterion)

EBL, endoscopic band ligation; Log Rank (Mantel-Cox), log-rank non-parametric test used to compare two survival curves, p=0.0001

During the presented waiting period for LT, 61 patients died. Mortality was associated with the VV bleeding development (in 14 patients from the EBL- treated group, and in 47 patients without interventions. Survival of patients was statistically significantly higher in the group of patients after EBL than in the group of patients without interventions, which was established using the Kaplan-Meier method (Log Rank =0.0001) (Fig. 2).

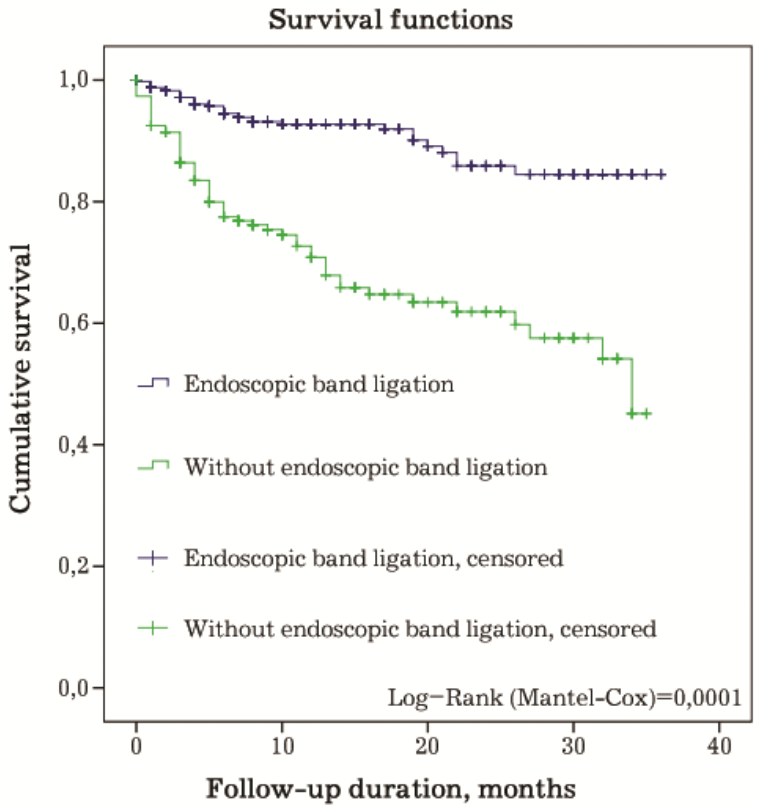

Fig. 2. Patient survival in the groups of patients treated with endoscopic band ligation or without intervention (Kaplan-Meier method with Log-Rank criterion)

EBL, endoscopic band ligation; Log Rank (Mantel-Cox), log-rank non-parametric test used to compare two survival curves, p=0.0001

Discussion

The development of esophageal VVs is one of the most significant consequences of PH due to their possible rupture followed by catastrophic bleeding [14], which is the main cause of death in patients with cirrhosis, including those waiting for LT [15]. Approximately one third of patients with compensated cirrhosis and almost 90% of patients with severe decompensated cirrhosis are found to have VVs [16]. The development of bleeding from VV with existing ascites is an extremely unfavorable factor

that increases the likelihood of death due to progressive cirrhosis decompensation [1, 2].

It is known that differences in the etiology and severity of cirrhosis can affect the outcomes of the disease, in particular, the development of VV bleeding [17]. In our study, the two groups of patients had no significant differences in the etiology of cirrhosis (viral, alcoholic), and they were comparable in terms of the MELD-Na score and CTP classes reflecting the severity of the disease. The presence of severe ascites (of the 2nd or 3rd degree) predetermined the necessity of the screening endoscopy as recommended by the International Baveno VI and VLL Consensus Workshop experts [1, 8]. Identification of VVs qualified as grade 2 and 3 VNT in patients with no bleeding prior to inclusion in LTWL led to choosing the strategy for the primary prevention of this LC complication [1, 18]. Since the study included patients who discontinued NSBB for various reasons (presence of contraindications for their use, intolerance, low systolic blood pressure and/or heart rate), we used EBL as a recommended alternative method for primary prevention of bleeding in the presence of ascites and threat of bleeding [1, 8, 18]. The group of patients without intervention consisted of patients who either refused from EBL procedure or showed no technical feasibility of its performance. Our study confirmed the high efficacy of the EBL technique for this patient category in reducing the incidence of bleeding from the upper GI tract and the bleeding-associated mortality as compared to patients without intervention, which is consistent with the data presented by S. Vadera et al. [17].

We consider it important to demonstrate the possibility of saving lives and preventing the dropout of patients with ascites during the long-term waiting for LT due to a donor organ shortage.

One of the shortcomings of our study is the lack of early diagnosis of PH progression by measuring the intrahepatic venous pressure gradient or determining the changes over time in stiffness by means of liver elastography, which would optimize the timing of intervention in patients with ascites awaiting LT.

Conclusions

1. The presence of varices in patients with ascites included in the liver transplantation waiting list is associated with the risk of bleeding, threatening with the development of rapid decompensation of liver cirrhosis and death while waiting for this operation.

2. Endoscopic band ligation effectively reduces the incidence of bleeding from the upper digestive tract, and the mortality associated with the occurrence of venous varix bleeding.

3**.** Endoscopic band ligation should be considered as a method of primary prevention of bleeding in patients with liver cirrhosis having a high risk of venous varix rupture in case of intolerance or contraindications to the use of non-selective β- blockers.

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